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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

- - - - - x
IN RE: NEW ENGLAND COMPOUNDING MDL No. 2419
PHARMACY, INC. PRODUCTS Master Dkt.
LIABILITY LITIGATION 1:13-md-02419-RWZ

- - - - - x
THIS DOCUMENT RELATES TO ALL SUITS
AGAINST THE SAINT THOMAS ENTITIES

- - - - - x
THIS DOCUMENT RELATES TO
ALL CASES

VIDEOTAPED DEPOSITION OF FRANCIS MCATEER

Wednesday, June 3, 2015

9:10 a.m.

Nutter McClennen & Fish LLP

Seaport West

155 Seaport Boulevard

Boston, Massachusetts 02210

Michelle Keegan, Court Reporter



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1 time we were there.

2 MR. ELLIS: Exhibit 310.

3 (Exhibit Number 310

4 marked for identification)

5 Q. This is an e-mail from Mike Cotugno to Barry
6 Cadden, cc Fran McAteer, re NECC visit, dated Thursday,
7 May 3rd, 2012.

8 MR. ELLIS: For the record, it's BW_118.

9 Q. So this is the next e-mail we could find in the
10 documents. So this is Michael, and he says to Barry --
11 Michael Cotugno saying to Barry Cadden, "I just wanted
12 to make sure we are still on for the BWH vendor audit on
13 Friday, May 4th, at 8:30." Do you see that?

14 A. Uh-hmm.

15 Q. This is the day before the site visit is about
16 to occur. Correct?

17 A. Yup.

18 Q. The group from BWH is going to be Cotugno and
19 Fran McAteer. Correct?

20 MS. ALESSI: Excuse me. He doesn't have the
21 page that you're reading from in front of him.

22 MR. ELLIS: I'm sorry. Did I just switch pages
23 here?

24 A. I think we just got one.

1 area which is marked on the blueprint as "shipping and
2 receiving" and back towards that warehouse area --

3 A. Right over here?

4 Q. Do you see that?

5 A. This area right here.

6 Q. And those actually join. That's open.

7 A. Right.

8 Q. I don't know if you remember, but the
9 shipping/receiving area opens into the warehouse area in
10 the back.

11 A. That's right. It did do that. That's some
12 sort of asphalt in there too.

13 Q. And then the second clean room is in the back.

14 A. Okay. Shown right there.

15 Q. So did you actually, like, look around the
16 boilers and the roof and the walls of the facility?

17 A. No. We just did a facility tour to get a
18 general layout and make some observations in the windows
19 to the clean rooms.

20 Q. So you didn't do an examination where you would
21 have seen discolorization of equipment or spaces in the
22 roof?

23 A. No, sir. We would have made -- and probably
24 the warehouse and the shipping/receiving area may have

1 been full of goods or equipment. We were a little bit
2 more concerned with segregation, restricted access, and
3 things of that nature.

4 Q. So this really was not to look at the real
5 condition of that building?

6 A. No. It certainly sends the wrong signal.

7 Q. Right. These photographs don't look great, do
8 they?

9 MR. WOLK: Objection.

10 A. No. But they are in noncritical space.

11 Q. And I'm not saying they're inside the clean
12 room. They're not. This is outside the clean room.

13 A. Yes.

14 Q. But you didn't see any of what's depicted in
15 these photos?

16 A. I did not see anything.

17 Q. And just to be clear, that big clean room in
18 the center of the blueprint that you're looking at, you
19 never went inside that, did you?

20 A. We did not go inside that.

21 Q. Now, they have changed their operation
22 completely?

23 A. Right.

24 Q. They had moved into this new clean room.

1 There's a freight anteroom that's -- I don't know if
2 it's ISO -- I can't read that, what it is -- 8. There's
3 a prep room that's ISO 7. There's a personal anteroom,
4 the gowning room, which ISO 7. You have a clean room
5 right in the center.

6 You hadn't seen that before?

7 A. We hadn't been inside the rooms. We had seen
8 this layout at Ameridose.

9 Q. Right.

10 A. Yes.

11 Q. Because Ameridose was building it in 2006.

12 A. That's right.

13 Q. So you get there. Did you ask to go into the
14 clean room?

15 A. Back then, sir, that just was not something
16 that was allowed.

17 Q. So my question is, did you ask to go -- In the
18 2012 visit, did you ask Barry Cadden: Can we go into
19 your clean room?

20 A. No, we didn't. It wasn't one of our methods of
21 operation for the audit at those dates.

22 If I can amend, we certainly make that as of
23 the -- after the post meningitis --

24 Q. So you changed your procedures on these audits

1 after the outbreak?

2 A. That's correct. We were, like everyone else,
3 in a reactive-type mode.

4 MR. TARDIO: I didn't hear.

5 THE WITNESS: I said, like everyone else, we
6 were in a reactive mode and we looked to make our
7 procedures more robust. Sorry.

8 Q. So for instance, you didn't see anything like
9 this inside the clean room. Exhibit 314, just this one
10 photo.

11 (Exhibit Number 314
12 marked for identification)

13 Q. I mean, from the --

14 A. No.

15 Q. I said you could look in a little bit from the
16 window, but you can't see a whole lot from looking in
17 that outside window, can you?

18 A. That's correct.

19 Q. You really couldn't see the condition of the
20 floors and the walls and the ceilings?

21 A. Right.

22 Q. You couldn't see if there were spaces in the
23 tiles in the ceilings, could you?

24 MS. ALESSI: Objection.

1 A. We were probably at least amenable to that
2 first part to be able to get a little bit more of that
3 detail.

4 Q. But you certainly couldn't see it all
5 throughout the whole clean room?

6 A. That's correct.

7 Q. So when you testified that the materials of use
8 in the clean room -- when you testified on direct that
9 the materials seemed adequate, you didn't see dirt, you
10 didn't see discoloration, well, you didn't go into the
11 key area. Correct?

12 A. That's correct.

13 MR. TARDIO: I object to the form.

14 Q. This is the clean room that the contaminated
15 drugs were made in.

16 MS. KELLY: Objection.

17 MR. WOLK: Objection.

18 A. I would have been happy to go in, but --

19 MS. ALESSI: There's no question.

20 Q. He wouldn't let you in, would he?

21 A. That's correct.

22 Q. He was not going to let you in no matter what.

23 MS. KELLY: Objection.

24 MR. WOLK: Objection.

1 compliance with 797 or not. Correct?

2 A. It's certainly an internal quality procedure
3 that NECC could have utilized.

4 Q. Well, you could have utilized it too. There
5 are gaps analysis tools. Correct?

6 MR. TARDIO: Objection to form.

7 A. I would utilize that for my clients.

8 Q. Right. You do it for Brigham and Women's
9 internal pharmacy. Correct?

10 MS. ALESSI: Objection.

11 A. Yes.

12 Q. You didn't do it for NECC during the 2012 site
13 visit?

14 A. It would have been beyond the scope of this.

15 Q. You never could have done that in 3 hours,
16 could you?

17 MR. WOLK: Objection. You got to let the
18 witness answer the question.

19 A. That's correct. I wouldn't be able to.

20 MR. WOLK: He needs to finish the answer.

21 MR. ELLIS: I apologize.

22 Q. You did not do a gap analysis of NECC's USP 797
23 compliance during the 2012 site visit to NECC, did you?

24 A. A gap analysis was not done on NECC because it

1 was not in the scope of the audit or our responsibility.

2 Q. But you did do it for Brigham and Women's
3 internal pharmacy. Correct?

4 MS. ALESSI: Objection.

5 A. That's correct.

6 Q. You did not take any surface samples for
7 testing and bring back to Microbiology Research
8 Associates where you could have tested some samples, did
9 you?

10 A. That again was beyond the scope of the audit
11 and would be an NEC contractual agreement with MRA.

12 Q. You did not review test results for viable
13 particles, did you?

14 MS. ALESSI: Objection.

15 A. I saw environmental monitoring reports.

16 Q. But you didn't actually look for the test --
17 the primary test results for viable particles, did you?

18 A. What NECC produced is what I saw.

19 Q. You did not observe the aseptic processing
20 occurring in the clean room, did you?

21 A. Right. It may have been that at the time we
22 were doing the walk-through there was no dynamic
23 conditions ongoing.

24 Q. You did not -- Do you know when Brigham and

1 A. No. And --

2 MS. KELLY: Objection.

3 Q. That's fine. I just wanted to know whether you
4 knew.

5 A. Yeah. And I think it was tempered around
6 whatever the Brigham and Women's drugs that would --
7 their CSPs that were being made.

8 Q. And by the way, since you didn't go into the
9 clean room, I take it that you did not verify that they
10 were using biological indicators to ensure that the
11 autoclave was performing satisfactorily in the compounds
12 when they were sterilized?

13 A. They could have been using it, sir. I'm not
14 aware of it.

15 Q. As you sit here today, you don't know whether
16 NECC was even using biological indications?

17 A. That's correct. I'm not sure sterilization was
18 applicable to any of Brigham and Women's products --
19 steam sterilization.

20 Q. Steam. Okay. If you didn't know it, you
21 didn't know it. Okay.

22 Now, let's turn back. Prior to either one of
23 these site visits, either the 2008, 2012, you were aware
24 of the FDA alert that they had issued on compounding

1 "And any vendor that wants your business
2 should be willing to allow you to talk to their
3 staff. We also are going to do an exhaustive
4 record review. And that's going to take some
5 time as well.

6 "And we're going to use a comprehensive
7 audit tool to document everything that we see
8 so that we can assure consistency in each site
9 visit that we do so that we're auditing each of
10 the vendors in the very same fashion and
11 looking for the very same information.

12 "I'm Bill Churchill" --
13 (End of recording)

14 BY MR. ELLIS:

15 Q. Mr. McAteer, when you did the site visits to
16 NECC in 2008 or 2012, did you ask to talk to the staff
17 at the facility in private without their boss sitting
18 there next to them?

19 A. No.

20 MS. KELLY: Objection.

21 Q. Did you have a conversation with Mr. Churchill
22 about that's really the way to really get to some real
23 information?

24 MS. KELLY: Objection.